

§ 423.1986

MAC review that is accepted and processed as specified in § 423.1974 and § 423.2100 through § 423.2130.

(e) *MAC review.* The revision of a MAC determination or decision is binding unless an enrollee files a civil action in which a Federal District Court accepts jurisdiction and issues a decision.

(f) *Appeal of only the portion of the determination or decision revised by the reopening.* Only the portion of the coverage determination, redetermination, reconsideration, or hearing decision revised by the reopening may be subsequently appealed.

(g) *Effect of a revised determination or decision.* Consistent with § 423.1978(c), a revised determination or decision is binding unless it is appealed or otherwise reopened.

§ 423.1986 Good cause for reopening.

(a) *Establishing good cause.* Good cause may be established when—

(1) There is new and material evidence that—

(i) Was not available or known at the time of the determination or decision; and

(ii) May result in a different conclusion; or

(2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

(b) *Change in substantive law or interpretative policy.* (1) *General rule.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision regarding appeals under this section.

(2) An adjudicator may reopen a determination or decision to apply the current law or CMS or the Part D plan sponsor policy rather than the law or CMS or the Part D plan sponsor policy at the time the coverage determination is made in situations where the enrollee has not yet received the drug and the current law or CMS or the Part D plan sponsor policy may affect whether the drug should be received.

(c) *Third party payer error.* A request to reopen a claim based upon a third

42 CFR Ch. IV (10–1–12 Edition)

party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

§ 423.1990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review.*

(1) For purposes of this section, a “review entity” means an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board, as determined by the Secretary.

(2) In order to obtain expedited access to judicial review (EAJR), a review entity must certify that the MAC does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute.

(3) An enrollee may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

(b) *Conditions for making the expedited appeals request.* (1) An enrollee may request EAJR in place of an ALJ hearing or MAC review if the following conditions are met:

(i) An IRE has made a reconsideration determination and the enrollee has filed a request for an ALJ hearing in accordance with § 423.2002 and a final decision, dismissal order, or remand order of the ALJ has not been issued; or

(ii) An ALJ has made a decision and the enrollee has filed a request for MAC review in accordance with § 423.2102 and a final decision, dismissal order, or remand order of the MAC has not been issued.

(2) The requestor is an enrollee.

(3) The amount remaining in controversy meets the threshold requirements established annually by the Secretary.

(4) If there is more than one enrollee to the hearing or MAC review, each enrollee concurs, in writing, with the request for the EAJR.

(5) There are no material issues of fact in dispute.